PHILIP MORRIS COMPANIES INC. INTER-OFFICE CORRESPONDENCE

1341 G STREET, N.W., SUITE 900, WASHINGTON, D.C., 20005

JUN 1 1993

Ken Houghton

TO: Distribution DATE: May 21, 1993

FROM: Kathleen M. Linehan

SUBJECT: Synar Bill

TO: K. Houghton

FYI

The Synar bill differs significantly from previous omnibus regulatory legislation which has been introduced. In this regard, I have attached a side by side comparing the Synar bill, the Kennedy bill of last Congress and the Waxman bill from two Congresses ago.

The new areas include:

- Providing HHS/FDA with authority to issue the most restrictive regulations possible, short of banning the product itself, for the manufacture, distribution, sale, labeling and advertising/promotion of tobacco products.

- Establishing an Advisory Committee to assist HHS/FDA in promulgating regulations in the same manner as other products that are ingested (food/drugs) are regulated. The Committee is also authorized to "review" other areas such as ETS, the use of additives, marketing techniques used by the manufacturers, and current federal, state and local laws governing tobacco.

- Granting FDA the authority to regulate advertising in a manner consistent with the regulation of prescription drugs.

- Granting HHS authority to require the manufacturers to provide additional information for labels or package inserts which would include information about adverse effects, "adequate warnings," contraindications, and adequate warnings against use in pathological condition.

- Establishing an annual manufacturing fee system based on market share requiring the industry to pay the cost of the new FDA program.

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Similarities to previously introduced bills include:

- A prohibition on low tar and nicotine claims, unless scientifically based and in the best interest of the public.
- A federal minimum age.
- A sampling ban.
- Public disclosure of all additives and constituents.
- Authority to the FDA to ensure that the additives are "safe."
- Authority to classify as "drugs" nicotine-containing products which are not traditional tobacco products.
- Authority to increase the size and placement of warnings.
- Partial preemption repeal which provides immunity from suit under state tort law.
- Use of FDA enforcement tools, i.e. seizures, injunctive relief, inspections, liability of corporate officers.
- A ban on industry sponsorship of sports, cultural or other public events.

Attachment

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